REMARKS

Claims 19-26 were rejected and remain pending. In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 19-26.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner maintained the rejection of claims 19-26 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled.

Applicants respectfully disagree. The following remarks are in response to the Examiner's arguments presented in the Official Action mailed June 3, 2005, and the Advisory Action mailed August 24, 2005.

First, a person having ordinary skill in the art reading Applicants' specification would have been able to make and use the presently claimed invention without undue experimentation. For example, no undue experimentation is required for a person having ordinary skill in the art to obtain a cell having a vector containing a drug-regulatable promoter operably linked to nucleic acid encoding a polypeptide. This is particularly true given that Applicants' specification discloses multiple drug-regulatable promoters that can be operably linked to nucleic acid encoding a polypeptide. *See, e.g.*, page 10, lines 9-12. In addition, no undue experimentation is required for a person having ordinary skill in the art to introduce those obtained cells into a mammal. In fact, a person having ordinary skill in the art could have easily infused or injected the cells into a mammal's blood stream as disclosed on page 20, lines 9-12 of Applicants' specification. Moreover, no undue experimentation is required for a person having ordinary skill in the art to increase expression of the polypeptide by altering the amount of regulatory drug to which the cells are exposed. This is particularly true given that many drug regulatable promoters were well known and characterized in the art. For example, the tetracycline-regulatable promoter is a promoter that was routinely used to regulate polypeptide expression in response to tetracycline. In addition, Applicants' specification discloses using a tetracycline-regulatable promoter to regulate polypeptide expression by altering the amount of tetracycline to which the cells are exposed. See, e.g., Example 1. Thus, taken together, Applicants' specification fully enables the presently claimed invention.

Second, the Examiner's attempt to distinguish the *In re Brana* case from the present case appears inconsistent with *Ex parte Jitka Forstova* (Appeal No. 1998-0667 Bd. Patent Appeals & Interferences, 2002 WL 32349992). Specifically, the Examiner stated that

> First the fact pattern is different; Brana is drawn to pharmaceutical compounds, while the instant invention is one of gene therapy. Second, the claims in Brana are drawn to a compound, while the claims of the instant application are drawn to a method of using nucleic acid sequences in gene therapy.

According to *Ex parte Jitka Forstova*, the principles of *In re Brana* apply equally to method claims relating to gene therapy. In fact, the U.S. Board of Patent Appeals and Interferences stated as much when reversing an enablement rejection similar to the present rejection:

> While the claims involved in Brana were directed to chemical compounds taught to be useful in treating cancer, we believe these principles can be applied to the claims at hand directed to methods of gene therapy, especially in light of the examiner's apparent holding that gene therapy in general is non-enabled.

See, Ex parte Jitka Forstova. Thus, under the proper standards as articulated by the Federal Circuit and the U.S. Board of Patent Appeals and Interferences, the present claims should be allowed. Applicants note that the Examiner, when addressing the specific subject matter of the presently claimed invention as opposed to making general statements about gene therapy, stated that the two steps recited in the present claims "may not require undue experimentation . . . ." *See*, page 4, lines 14-19 of the Official Action mailed June 3, 2005.

Even the art cited by the Examiner fails to support the Examiner's allegations that gene therapy is so unpredictable that a person having ordinary skill in the art can not practice gene therapy without undue experimentation. For example, the Crystal reference (*Science*, 270:404 (1995)) states that:

> [e]nough information has been gained from clinical trials to allow the conclusion that human gene transfer is feasible, can invoke biologic responses that are relevant to human disease, and can provide important insights into human biology.

See, first sentence of the Abstract. Although several sections of the cited references refer to apparent problems or obstacles in particular fact settings, the ability to overcome such problems

or obstacles is not the standard for enablement. In particular, the U.S. Board of Patent Appeals and Interferences stated that:

> a number of the quotes relied upon by the examiner from the references refer to problems or obstacles in delivering the therapeutic to the target in a clinical setting. However, as stated in Brana, that is not the standard for enablement and/or utility.

See, Ex parte Jitka Forstova.

In light of the above, Applicant respectfully requests the withdrawal of the rejection of claims 19-26 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 19-26 under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. Specifically, the Examiner stated that:

> The term altering in the context of claim one is equivalent to an open ended numerical range that encompasses any change in the amount of regulatory drug to which said cell is exposed. As such the term is indefinite.

Applicants respectfully disagree and submit that there is no *per se* rule that an open-ended term is indefinite. The second paragraph of 35 U.S.C. § 112 requires the specification to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." To determine whether this requirement is satisfied, one must ascertain whether the claims set out the subject matter with a reasonable degree of clarity and particularity. The definiteness of claim language must be analyzed in light of: (1) the content of Applicant's specification; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP § 2173.02. In fact, the Federal Circuit has repeatedly stated that analysis under 35 U.S.C. § 112, second paragraph "requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *See, e.g., Miles Laboratories, Inc. v. Shandon Inc.,*

997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993); and *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed Cir. 1986).

A person having ordinary skill in the art reading Applicants' specification and the present claims would have understood the meaning of the term "altering." In fact, the Examiner apparently had no problem understanding that the term "altering" encompasses "any change in the amount of regulatory drug to which said cell is exposed." Thus, taken together, the present claims are clear and not ambiguous.

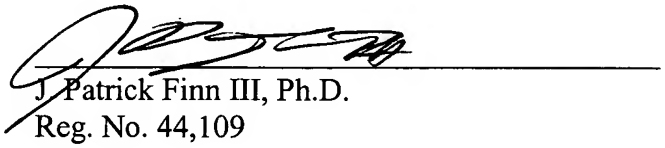
In light of the above, Applicants respectfully request the withdrawal of the rejection of claims 19-26 under 35 U.S.C. § 112, second paragraph.

CONCLUSION

Applicants submit that claims 19-26 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050.

Respectfully submitted,

Date: November 3, 2005



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